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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,520	05/03/2002	Eduardo Mitrani	01/22858	4334

7590 01/03/2006

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,520	MITRANI, E.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the communication filed 1/5/2005. The communication filed 1/5/2005 indicates that the Office Action mailed on 12/16/2005 was mailed an incorrect address. Upon closer evaluation, it appears that the Office had recorded the incorrect mailing address for the instant application due to a transposition of numbers in an application with a similar serial number. Therefore, Office Action mailed 12/16/2004 is hereby vacated.

The time period for response begins on the mailing date of this Office Action.

Claims 1-36 are currently pending in the application and are addressed herein.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a method of inducing angiogenesis in a tissue of a first mammal wherein the method comprises implanting at least one micro-organ for producing a plurality of angiogenic factors.

Group II, claim(s) 17-21, drawn to a method of inducing angiogenesis in a tissue of a first mammal wherein the method comprises extracting soluble molecules from a micro-organ and administering the extracted soluble molecules to the first mammal.

Group III, claim(s) 22, drawn to a pharmaceutical composition comprising a soluble molecule extract from a micro-organ.

Group IV, claim(s) 23-31, drawn to a micro-organ comprising a plurality of cells wherein the cells comprise an exogenous polynucleotide sequence.

Group V, claim(s) 32-36, drawn to method of inducing angiogenesis in a tissue of a first mammal wherein the method comprises generating a conditioned medium and administering the conditioned medium to the first mammal.

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I, is considered the main invention.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions are not linked by a special technical feature. In order for a technical feature to be a special technical feature it must be novel. In the instant case, the main invention, Invention I (a method of inducing angiogenesis in a tissue of a first mammal wherein the method comprises implanting at least one micro-organ for producing a plurality of angiogenic factors) is not novel. It is noted that the broadest embodiment of the main invention (i.e., claim 1) encompasses a method comprising administering to a patient a micro-organ which can be a single cell wherein the cell produces a plurality of angiogenic factors, and includes administering a cell or cells that have been transfected with a nucleic acid to express the plurality of angiogenic factors. Invention I is not novel because US Patent No. 5,980,887 (Isner et al.) teaches a method for inducing angiogenesis by isolating endothelial cells

from a patient, transfecting the cells to achieve constitutive expression of angiogenic cytokines and/or selected matrix proteins and transferring the transfected cells to the patient for treating a ischemia (e.g., see column 6, lines 16-65, especially lines 35-45; as well as column 3, lines 1-18; column 8, line 64 through column 9, line 6).

As indicated above, in order for a technical feature to be special, it must be novel. In the instant case, the invention of Group I is not novel. Therefore, there is no special technical feature linking Groups I-V.

Furthermore, Groups II and V are not linked to the main invention (Group I) because there is no unity of invention as Group II is drawn to administering a soluble extract and Group V is drawn to administering a conditioned medium. As such, these inventions involve different methods which have different method steps and require the use of different reagents, etc.

Groups III and IV are not linked to the main invention (Group I) because Group III is drawn to a soluble molecule extract and Group IV is drawn to a micro-organ. As indicated above, 37 CFR 1.475(b) indicates that the first Group must be a product in order for the combination of categories to have unity of invention. In the instant case Group I is a process while Groups III and IV are products. Therefore, unity of invention for the process of Group I and the products of Groups III and IV does not exist.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of organs from which the micro-organ is derived are as follows:

Lung, liver, kidney, muscle, spleen, skin, heart and other gut derived organs (see claims 4 and 26).

The species of exogenous polynucleotide sequences are as follows:

An enhancer polynucleotide sequence, and a suppressor sequence (see claims 14 and 30).

Applicant is required, in reply to this action, to elect a single species of organs from which the micro-organ is derived and a single species of exogenous polynucleotide sequence to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: The claims of group I and Group IV (i.e., claims 1-16 and 23-31) are generic for the indicated species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the different species have different functions. For instance lung cells, liver cells, kidney cells, muscle cells, spleen cells, skin cells, heart cells and

cells of other gut derived organs are all structurally different would all function differently when transferred into a patient. Also, enhancer polynucleotide sequences and suppressor sequences also clearly have different functions. It is noted, however, that each species would be obvious over the other species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

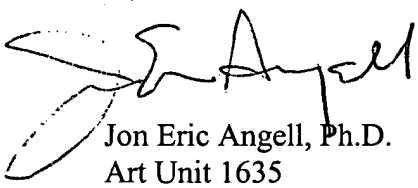
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

The present application was filed containing a power of attorney to Sol Sheinbein and Martin Moynihan. A correspondence address was supplied for Sol Sheinbein. No address was supplied for Martin Moynihan.

Sol Sheinbein was excluded from practice before the Patent and Trademark Office (Office). The Office does not communicate with attorneys or agents who have been suspended or excluded from practice.

As a correspondence address, other than to Sol Sheinbein, is not of record, this Office action is being mailed to the other practitioner of record at his/her last known address as listed on the register of patent attorneys and agents. To ensure that a copy of this Office action is received in a timely manner to allow for a timely reply, a copy of the Office action is being mailed directly to the address of the inventor first named in the declaration or oath. Any reply by applicant(s) should be by way of the remaining practitioner(s) of record and should include a new correspondence address.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
Art Unit 1635